



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/607,559

06/25/2003

Rhonda J. Honeycutt

11399-005-999

7286

41790

7590

05/31/2006

BUCHANAN INGERSOLL LLP
(INCLUDING BURNS, DOANE, SWECKER & MATHIS)
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,559

Applicant(s)

HONEYCUTT ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 4/14/2006 to the Office action has been entered. Claims 22-38 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 22-38 in the reply filed on 4/14/2006 is acknowledged.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 22-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,599,701. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 22-38 are drawn to a method of characterizing a target organism suspected of being a member of a given taxonomic group comprising the steps of selecting at least one

Art Unit: 1637

intronic region known to be found in some or all members of the taxonomic group, analyzing the intronic region of the target organism and comparing it to known intronic region characteristics of members of the taxonomic group. The method steps of the instant claims 22-38 are recited in claims 1-11 of U.S. Patent No. 6,599,701. Claims 1-11 of U.S. Patent No. 6,599,701 require more specific steps, for example, a first set of primers that are complementary to a consensus sequence in the intronic region is required. Thus, the instant claims 22-38 and the patented claims 1-11 are related as genus-species. Therefore, nonstatutory obviousness-type double patenting rejection is applicable.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 29-30 are vague and indefinite because of the phrase “intron insertion site”. It is unclear what is the definition in the specification. Clarification is required.
- b. Claim 31 is vague and indefinite because the primer used in the instant claims is an intronic region-specific primer, but the claim recites that the intronic region-specific primers are complementary to a sequence of nucleotides in an exon. It appears that the intronic region-specific primer is also specific to the exon. Clarification is required.

Art Unit: 1637

c. Claims 22-38 are vague and indefinite because the phrase "it" in claim 22. It is unclear what the phrase is referring. Clarification is required.

d. Claim 38 is vague and indefinite because the claim recites that the intronic region further comprises all or a portion of an open reading frame that encodes a protein. In general, the intronic region does not encode a protein. Clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 22-25, 27-28 and 32-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Montplaisir et al. (5,545,525, issued August 13, 1996).

Montplaisir et al. disclose the sequence of a small DNA fragment specific to *C. stellatoidea* and a subgroup of *C. albicans* which have been isolated and identified as a group I intron (See column 3, lines 1-5) (as recited "selecting at least one intronic region known to be found in some or all members of the taxonomic group" in claim 22(a)). The target organisms are analyzed via PCR, (See column 8, lines 13-42) with the primers, which are specific to the *Candida* intron sequence (See column 8, lines 39-43). The comparison step is done to known intronic region in which *C. albicans* intron displays a potential secondary structure comparable to all known group I intron (See column 5, lines 14-56 and column 6, lines 3-17, column 7, lines 26-28). The length of the intronic region is determined (See column 5, line 49-56). A specific

Art Unit: 1637

nucleic acid probe is hybridized to the amplified product (See column 3, lines 4-7 and column 9, lines 14-18). The intronic regions of 108 clinical strains identified as *C albicans* are analyzed by restriction fragment length polymorphism (See column 5, lines 8-13). The teachings of Montplaisir et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Montplaisir et al. (5,545,525, issued August 13, 1996) as applied to claims 22-25, 27-28 and 32-37 above, and further in view of Appleby et al. (GB 2 310 718).

The teachings of Montplaisir et al. are set forth in section 6 above. Montplaisir et al. do not disclose that the nucleotide sequence of the intronic region is determined.

Art Unit: 1637

Appleby et al. disclose that a process for the determination of the phylogeny of plant material comprises the characterization of at least one intron from ribulose 1,5-bisphosphate carboxylase (RuBisCo) encoding gene and comparison of the intron with at least one previously-characterized intron from a RuBisCo small subunit encoding gene. The intron may be sequenced and the length of introns is measured (See pg. 3, forth and fifth paragraph).

One of ordinary skill in the art would have been motivated to apply the sequence determination method as used by Appleby et al. because the method of Appleby et al. ¹⁵are capable of reproducibly amplifying a polymorphic section of the RuBisCo small subunit encoding gene from over twenty different species and regions comprising introns provide a useful tool for analysis in the plant kingdom (See pg. 16, last paragraph and pg. 17, last paragraph). It would have been prima facie obvious to determine the nucleotide sequence of the intronic region.

Summary

9. No claims are allowable.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. m*
May 19, 2006

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/25/06